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Titan Pharmaceuticals Receives Feedback From FDA on Ropinirole Implant Development Program for Parkinson's Disease

SOUTH SAN FRANCISCO, CA -- (Marketwired) -- 03/07/16 -- Titan Pharmaceuticals, Inc. (NASDAQ: TTNP) announced today that the U.S. Food and Drug Administration has provided written feedback on the initial development plan for its proprietary ropinirole hydrochloride (HCL) implant for Parkinson's disease. Based on the FDA's feedback on the development plan submitted in December 2015, Titan is proceeding with the required non-clinical studies to support the potential submission of an investigational new drug (IND) application in the fourth quarter of 2016, followed by the initial pharmacokinetic and proof-of-concept clinical study. Titan is pursuing a 505(b)(2) registration pathway for the product candidate.

The ropinirole implant, which employs Titan's novel ProNeura technology platform, is designed for the long-term, continuous delivery of ropinirole HCL for the treatment of signs and symptoms of Parkinson's disease, including stiffness, tremors, muscle spasms, and poor muscle control. Ropinirole is a dopamine agonist currently available in daily or more frequently dosed oral formulations for the treatment of Parkinson's disease symptoms and restless leg syndrome.

The U.S. patent for Titan's ropinirole implant, which was allowed last year, is scheduled to be issued on March 8, 2016.

"Our early studies of a ropinirole implant utilizing the ProNeura technology have shown promise, and we are encouraged by the FDA's feedback on the product development plan ahead of an IND filing later this year," said Kate Beebe Ph.D., Titan's chief development officer and executive vice president. "Parkinson's disease affects nearly one million people in the U.S., a number that is rapidly increasing with the aging population. Symptoms of the disease can be very debilitating, and more treatments are needed to improve the quality of life for these patients until a cure is found."

In June 2015 Titan presented nonclinical data from a dose-escalating study of a ropinirole implant in a Parkinsonian primate model at the 19th International Congress of Parkinson's Disease and Movement Disorders. The study showed that motor function could be significantly improved with no onset of dyskinesias (involuntary movements), following the continuous, non-fluctuating release of ropinirole with the subdermal implant. There were also no observed signs of irritation, inflammation or fibrotic capsule formation at the implant site. Continuous, non-fluctuating release of ropinirole was observed for a period of several months following implantation.

Symptoms of Parkinson's disease are primarily treated today by dopamine replacement therapy (DRT). However, DRT is often associated with the pulsatile stimulation of dopamine receptors due to peak-trough fluctuations of medication in the blood. Over time the non-physiologic stimulation of dopamine receptors in the brain causes patients to develop serious motor complications and dyskinesias, limiting treatment effectiveness. Current treatments that offer continuous delivery of medication providing non-pulsatile stimulation of dopamine receptors in the brain appear to be more effective in controlling motor complications, but are surgically invasive and with potential risk of serious adverse effects.

Titan's ropinirole implant will be inserted subdermally in a brief office procedure and could potentially provide continuous, non-fluctuating therapeutic drug levels for several months from a single treatment. Probuphine, the company's first product utilizing the ProNeura long-term continuous drug delivery platform, has demonstrated safety and efficacy in a Phase 3 clinical program for the maintenance treatment of opioid addiction, and a new drug application (NDA) is currently under review by the FDA with an action date of May 27, 2016.

About the ProNeura Long-term Drug Delivery Platform

ProNeura is Titan's proprietary, long-term drug delivery platform utilized in the development of products for the treatment of select chronic conditions that may benefit from the delivery of continuous, non-fluctuating levels of certain medications over an extended period of six months to a year. ProNeura consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inner part of the upper arm, during a simple office procedure, and is removed in a similar manner at the end of treatment. The drug substance is released continuously through the process of dissolution, resulting in a stable, non-fluctuating blood level similar to that seen with intravenous administration. These long-term, linear-release characteristics are medically desirable to avoid the peak and trough swings from oral dosing that pose problems in the current treatments for many diseases, especially diseases of the central nervous system. Titan has issued patents as well as patent applications covering the use of the ProNeura long-term drug delivery platform for the formulation of specific products for the treatment of certain chronic diseases, such as opioid addiction, Parkinson's disease, and others.

About Titan Pharmaceuticals

Titan Pharmaceuticals Inc. (NASDAQ: TTNP), based in South San Francisco, CA, is a specialty pharmaceutical company developing proprietary therapeutics primarily for the treatment of serious medical disorders. The company's lead product candidate is Probuphine®, a novel and long-acting formulation of buprenorphine for the long-term maintenance treatment of opioid dependence. Probuphine employs Titan's proprietary drug delivery system ProNeura™, which is capable of delivering sustained, consistent levels of medication for three months or longer. Titan has granted U.S. and Canadian commercial rights for Probuphine to Braeburn Pharmaceuticals. If approved, Probuphine would be the first and only commercialized treatment of opioid dependence to provide continuous, around-the-clock blood levels of buprenorphine for six months following a single procedure. The ProNeura technology has the potential to be used in developing products for treating other chronic conditions, such as Parkinson's disease, where maintaining consistent blood levels of a therapeutic agent may benefit the patient and improve medical outcomes. For more information about Titan, please visit www.titanpharm.com.

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the regulatory approval process, the development, testing, production and marketing of our drug candidates, patent and intellectual property matters and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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